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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,994	09/07/2001	Yuqing E. Chen	B0801/7197 ERG	9185

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Edward R Gates
Wolf Greenfield & Sacks
Federal Reserves Plaza
600 Atlantic Avenue
Boston, MA 02210-2211

EXAMINER	
ASHEN, JON BENJAMIN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,994	CHEN ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-98 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-98 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11 are drawn to a nucleic acid encoding the CNREB-2 protein.

Group II, claim(s) 12-16 and 20 are drawn to isolated CNREB-2 protein.

Group III, claim(s) 17-19 are drawn to an isolated binding polypeptide that selectively binds CNREB-2 protein.

Group IV, claim(s) 21 is drawn to a method of isolating a nucleic acid encoding the CNREB-2 protein.

Group V, claim(s) 23-38 are drawn to a method of using an antisense oligonucleotide as a CNREB-1 inhibitor to decrease rennin expression in a cell or in a subject.

Group VI, claim(s) 23-38 are drawn to a method of using a dominant negative nucleic acid as a CNREB-1 inhibitor to decrease rennin expression in a cell or in a subject.

Group VII, claim(s) 40-41, 44-48 and 51-54 are drawn to a method of increasing CNREB-1 activity in a mammalian cell or subject using a nucleic acid as the CNREB-1 activator agent.

Group VIII, claim(s) 42-46 and 49-54 are drawn to a method of increasing CNREB-1 activity in a mammalian cell or subject using a polypeptide as the agent.

Group IX, claim(s) 56, and 58-60 are drawn to a method of determining the level of CNREB-1 expression in a subject by measuring the level of CNREB-1 mRNA expression.

Group X, claim(s) 57-60 are drawn to a method of determining the level of CNREB-1 expression in a subject by measuring the level of CNREB-1 protein expression.

Group XI, claim(s) 62-68, 70, 72-79 are drawn to a method of determining a subject's susceptibility to developing a rennin-angiotensin system mediated disorder using hybridization to detect alterations in test sample CNREB-1 nucleic acid sequences as compared to those of a control.

Group XII, claim(s) 62-64, 69 and 71-79 are drawn to a method of determining a subject's susceptibility to developing a rennin-angiotensin system mediated disorder using PCR to detect alterations in test sample CNREB-1 nucleic acid sequences as compared to those of a control.

Group XIII, claim(s) 81, 83-84 are drawn to a method of using a CNREB-1 modulator to modulate c-myc expression in a cell using a nucleic acid.

Group XIV, claim(s) 82-84 are drawn to a method of using a CNREB-1 modulator to modulate c-myc expression in a cell using a polypeptide.

Group XV, claim(s) 86, 88-89 are drawn to a method of using a CNREB-1 modulator to modulate collagen Type II expression in a cell using a nucleic acid.

Group XVI, claim(s) 87-89 are drawn to a method of using a CNREB-1 modulator to modulate collagen Type II expression in a cell using a polypeptide.

Group XVII, claim(s) 91, 93- 94 are drawn to a method of using a CNREB-1 modulator to modulate T cell Receptor expression in a cell using a nucleic acid.

Group XVIII, claim(s) 92- 94 are drawn to a method of using a CNREB-1 modulator to modulate T cell Receptor expression in a cell using a polypeptide.

Group XIX, claim(s) 96 –98 are drawn to a composition comprising a CNREB-1 inhibitor wherein the CNREB-1 inhibitor is an antisense oligonucleotide.

Group XX, claim(s) 96 –98 are drawn to a composition comprising a CNREB-1 inhibitor wherein the CNREB-1 inhibitor is a dominant negative nucleic acid of CNREB-1.

2. Claim 22 link(s) inventions of group V and group VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 22. Claim 39 link(s) inventions of groups VII and group VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking

claim(s), claim 39. Claim 55 link(s) inventions of group IX and X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 55. Claim 61 link(s) inventions of group XI and XII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 61. Claim 80 link(s) inventions of group XXII and XXIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 80. Claim 85 link(s) inventions of group XXIV and XXV. Claim 90 link(s) inventions of group XXVI and XXVII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 90. Claim 95 link(s) inventions of group XXVIII and XXIX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 95.

3. Claims 23-38 are generic to groups V and VI. Claims 44-46, 51-54 are generic to groups VII and VIII. Claims 58-60 are generic to groups IX and X. Claims 62-64 and 72-79 are generic to groups XI and XII. Claims 83-84 are generic to groups XIII and XIV. Claims 88-89 are generic to groups XV and XVI. Claims 93-94 are generic to groups XVII and XVIII. Claims 96-98 are generic to groups XIX and XX. These claims will be examined limited to the groups selected

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s)

depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claims 26, 41, 43, 48, 50, 65 and 98 recite "from the group consisting of the nucleic acid of SEQ ID NO: 1, the nucleic acid of SEQ ID NO: 3, the nucleic acid of SEQ ID NO: 5 and the nucleic acid of SEQ ID NO: 6."

Claim 37 recites, "wherein the agent is selected from the group consisting of ..." and then lists five "agents."

Claim 54 recites, "wherein the agent other than ... is selected from a group consisting of ..." and then lists nine agents.

Claim 77 recites, "wherein the tissue is selected from the group consisting of ..." and then lists 24 tissues.

Claim 79 recites, "wherein the biological fluid is selected from a group consisting of ..." and then lists 21 fluids.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Under rule 13 there is unity of invention between an independent claim for a composition, an independent claim for preparing a composition and an independent claim for using the composition.

Group I contains an independent claim to the nucleic acids encoding CNREB-2 protein, an expression vector comprising said nucleic acids and host cells transformed with said vector. Group II contains an independent claim to an isolated polypeptide that has CNREB-2 activity. Group III contains an independent claim to an isolated binding protein that selectively binds CNREB-2 protein and Group IV contains an independent claim to a method of isolating a nucleic acid encoding the CNREB-2 protein.

Groups (V-XIX) are drawn to methods relating to the CNREB-1 protein and its expression or to a composition comprising an inhibitor of the CNREB-1 protein. As recited in the specification, "Analysis of the sequence by comparison to nucleic acid and protein databases show that CNREB-2 shares no significant homology with any other known gene or protein" and "Analysis of the sequence [of CNREB-1] by comparison to nucleic acid and protein databases show that CNREB-1 shares high homology to the *Rattus norvegicus* orphan receptor RLD-1 (SEQ ID NO:5, 93% homology at the nucleotide level), and to the human nuclear orphan receptor LXR-α (SEQ ID NO:6, 89% homology at the nucleotide level)." The CNREB-1 and CNREB-2 as described are different proteins that differ in nucleic acid sequence such that they have different chemical structures. As a result, CNREB-1 and CNREB-2 are not clearly interchangeable in all of their biological activities and cannot constitute a common, special technical feature linking the methods related to the CNREB-1 protein to the compositions related to the CNREB-2 protein. Therefore, the claims of groups I-XX do not relate to a single inventive concept under PCT rule 13.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 517-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jba

SEAN McGARRY
PRIMARY EXAMINER
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